

April 7, 2000

Mr. William Maloney
Diagnostic Branch (HFZ-322)
Division of Enforcement I
Office of Compliance
Center for Device and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

Dear Mr. Maloney:

The purpose of this letter is to request a variance for the FluoroScan Premier mini C-Arm, from a provision of 21 CFR 1020.32 (g) requiring that products shall be provided with a means to limit the source-skin distance (SSD) to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image-intensified fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters.

The following information is being provided as outlined in 21 CFR 1010.4 (b), "Applications for variances".

- i) **Description of Product:** The Premier is a mobile, cabinet mounted, image intensified, digital mini C-Arm fluoroscopic x-ray system intended for surgical and non-surgical examinations of extremity body parts. See attachment (A) for detailed description and comparison to other mini C-Arms for which variances have been granted. Informal classification of the unit as a small hand held device used to assess sports injuries on the playing field are incorrect and do not represent any of the devices manufactured and marketed by FluoroScan Imaging Systems.
- ii) **Explanation of How Compliance Would Restrict Intended Use:** Compliance with current limitations of permissible S.S.D.s such as those imposed on large, mobile, image intensified fluoroscopes would restrict intended use. Doing so would require that the available free space of the PREMIER mini c-arm be reduced, or that the size of the c-arm be increased. Reducing the available free space would severely limit the utility of the mini c-arm for its intended purpose. At the same time, increasing the size of the c-arm to preserve the free space would compromise the safety aspect of the mini c-arm by requiring the use of a larger, more powerful x-ray tube.
- iii) **Proposed Deviation from Requirements:** FluoroScan's proposed deviation from the requirement is to reduce the minimum source-skin distance to nine (9) centimeters. This is identical to that of the existing products currently manufactured under variance number 84V-0380 by our company. It is also the same source-skin distance approved under variance number 95V-0276 for the OEC model number 6600 mini C-Arm.
- iv) **Advantages Derived from Deviation:** The limitation of the Premier's x-ray output and the geometry of its c-arm are interrelated and have been balanced to optimize the system's utility and to provide a high level of safety for both the patient and the system operator. On one side of the equation is the need to keep the overall S.I.D. as small as possible so smaller x-ray sources producing conservative levels of x-ray can be used. On the other side of the equation is the need for a relatively large free space and C-arm depth to accommodate the part being imaged along with other necessary objects and implements.

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VAR 1

Recall that the primary application of the Premier mini c-arm is the surgical and non-surgical examination of extremity body parts. These body parts not only vary with the size of the patient, but may also include or be impeded by traction devices, internal and/or external fixation devices, casts and splint materials introduced before during or after a procedure. While being imaged by a mini c-arm fluoroscope, an extremity can easily take up much more space than the actual body part itself. In this context, one can see why mini c-arms with large free spaces are preferable to mini c-arms with small ones.

- v) **Alternate Means of Radiation Protection:** Suitable means for radiation safety and protection will be provided by constraints on the design and by supplemental information and labeling provided to users. The design constraints will be similar to those for the FSIII, (See Attachment A). The supplemental information and labeling will be identical to FSIII.
- vi) **Time Limit of Variance:** We request that this variance be in effect for a period of five (5) years or until the effective date of any new regulations concerning small format c-arm x-ray systems, whichever comes first.
- vii) **Prototype and Experimental Equipment Location:** All prototype and experimental equipment will be located in our factory. See letterhead for address.
- viii) **Other Information Required by CDRH:** A copy of the Initial Report for this product is attached for your review. See attachment B.
- ix) **Nonclinical Laboratory Studies:** No Nonclinical laboratory studies were conducted.
- x) **Reserved**
- xi) **Electronic Products Used in Clinical Investigation Involving Human Subjects:** The Premier is not used in clinical investigations involving human subjects.

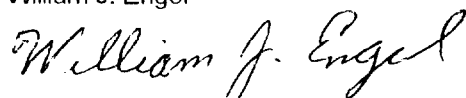
As you know from our recent telephone conversations, the Premier has been manufactured under an existing variance number 84V-0380. This was reported in our initial report, reference number (8511719-22), dated September 28, 1998. In a recent request to extend this variance, you and Mr. Knox informed me that you could not include the Premier on the existing variance because in your opinion it did not meet the requirements of 21 CFR 32 b 2 iv. The attached supplement to our initial report, submitted on April 5, 2000 indicates how future production of Premier will meet this regulation. (See Attachment B).

FluoroScan is currently in the process of developing plans to address the existing systems in the field in regards to compliance to 21 CFR 32 b 2 iv. We will submit these plans as soon as they are complete.

I hope you will find the information in this report sufficient to issue a variance letter for the Premier system. If you require any other information or have any questions, please feel free to call.

Sincerely,

William J. Engel



Manager, QA & Regulatory Affairs

ATTACHMENT (A)

Comparison Chart Between Premier, FSIII and OEC 6600

X-Ray Source Assembly	FluoroScan Premier	FluoroScan III	OEC Mini 6600
<i>Type</i>	Fixed Anode, Tungsten Filament	Fixed Anode, Tungsten Filament	Fixed Anode, Tungsten Filament
<i>Target Angle</i>	17 Degrees	17 Degrees	13.5 Degrees
<i>Maximum Technique Factors</i>	75 kV and 100 uA	75 kV and 100 uA	75 kV and 100 uA
<i>X-Ray Tube Rating</i>	75 kV (Rated Peak Tube Potential)	75 kV (Rated Peak Tube Potential)	80 kV (Rated Peak Tube Potential)
<i>Filament Rating Continuous</i>	2.2 A Typ. 2.4 A max.	2.2 A Typ. 2.4 A max.	1.57 VDC/2.28 Amps max.
<i>Output Emission Current</i>	20 - 100 uA	20 - 100 uA	20 - 100 uA
<i>Duty Cycle</i>	Continuous	Continuous	Continuous
Imaging Dimensions	FluoroScan Premier	FluoroScan III	OEC Mini 6600
<i>Depth of C-arm</i>	36 cm (14 in)	25.4 cm (10in)	36.9 cm (14.5 in)
<i>Source Image Distance (SID)</i>	44 cm (17.5 in)	70 mm - 35.5cm (14.2in)	40.13 cm (15.8 in)
		100mm - 36.5cm (14.4 in)	
<i>Free Space</i>	35 cm (14 in)	70mm = 26.5 cm (10.4in)	30.48 cm (12.0 in)
		100mm= 35.0 cm (13.8in)	
<i>Source-Skin Distance (SSD)</i>	9 cm	9cm	9 cm
<i>Max. EER at Min SSD</i>	4.60R/Min.	4.70R/Min.	5.109R/Min.

ATTACHMENT (B)

Part 100 - Identification

101.0 Report Identification

This report is submitted pursuant to 21 CFR, Part 1002.61, paragraphs (c) (2).

Date: April 4, 2000

Report Type: Supplement to Initial Report Number 8511719

Manufacturer: FluoroScan Imaging Systems
650-B Anthony Trail
Northbrook, IL 60062

Submitter: FluoroScan Imaging Systems

Corresponding Official: William J. Engel

The purpose of this document is to update the FluoroScan product report for the Premier system. The following sections of this report have been changed from what was previously submitted:

Appendix

A, B, C, and I

Part 200

202.1, 202.6.a, 202.6.b, 202.7.a, 202.7.b, and 203.5.f

Part 300

Prototype testing for the following sections was conducted with the new smaller, lead ring used in the beam-limiting device:

301.4, 302.4, 305.4, 306.4, 308.4, and 321.4

102.0 Product Identification

102.1 The system model number is (60000). The system is a Mini C-arm consisting of the following certifiable components:

<u>Certifiable Component Type</u>	<u>Model Designation</u>
X-ray High Voltage Generator	FS IV HVG
X-ray Tube Housing	FS IV TH
Beam Limiting Device	FS IV BLD
Image Intensifier Module	TH 9449
X-ray Control	340

102.2	<u>Certifiable Combination</u>	<u>Model Number</u>
	High Voltage Generator	FS IV HVG
	Tube Housing	FS IV TH
	Beam Limiting Device	FS IV BLD

102.3 N/A

102.4 See Appendix A

102.5 System Designation: FS IV, Model Number (60000)

<u>Component Type</u>	<u>Model Designation</u>	<u>Manufacturer</u>
1) X-ray High Voltage Generator/Tube Housing	N/A	FluoroScan
2) X-ray Tube	E70105	Kevex
3) Beam Limiting Device	FS IV BLD	FluoroScan
4) Image Intensifier	TH 9449	Thomson
5) X-ray Control	340	FluoroScan

102.6 See Appendix B (New Manual)

102.7 See Appendix C. (New Manual)

Part 200 - Component Description

201.0 Tube Housing Assembly

- 201.1 The maximum rated peak tube potential for the tube housing referenced in this report is 75kVp.
- 201.2 N/A
- 201.3 Each x-ray tube has a permanently etched serial number on the focusing cup inside the glass envelope. A label which indicates the model number and serial number of the tube is affixed to the tube housing. Upon removal of a tube, the label is removed from the housing and applied to the outer envelope of the removed tube. The replacement tube is installed and its label, indicating the model and serial numbers, is affixed to the tube housing.
- 201.4 See Sections 301.0 and 302.0

202.0 Beam Limiting Devices

- 202.1 Applications: General purpose fluoroscopy, of extremities only.
- 202.2 through 202.5 - N/A
- 202.6 Beam Limiting Devices used with Fluoroscopy
 - a. Collimators are factory adjusted to provide a circular x-ray field of 122 sq. cm, which is well within the 15 cm diameter circular visible area of the image receptor. Collimation is not user adjustable.
 - b. The x-ray field at the SID of 44 cm is 12.5 cm in diameter.
 - c. N/A
 - d. See 321.0, Part 300
 - e. The FluoroScan Imaging System identified in this report is a mobile fluoroscope with a SSD of 9 cm manufactured under variance number 84V-0380.
 - f. The SSD limiting block is permanently affixed to the tube housing cover.
 - g. No means for system failure override are provided.
- 202.7 X-ray System designed for One SID and Image Receptor Size Combination
 - a. The Beam Limiting Device, Model Number FS IV BLD, is designed such that, when used with a SID of 17.5", it will collimate well within the image receptor size of 15 cm.

b. Collimators are factory adjusted to provide a circular x-ray field of 12.5 cm diameter centered on the 15 cm diameter circular visible area of the image receptor.

c. N/A

d. N/A

e. See Section 319.0, Part 300.

202.8 N/A

202.9 N/A

202.10 The Beam Limiting Device identified in this report is designed to operate at a maximum kVp of 75 kVp.

202.11 N/A

202.12 See Section 301.0, Part 300.

202.13 See Section 302.0, Part 300.

202.14 N/A

203.0 X-Ray Controls

203.1 Applications:
General Purpose Mobile Fluoroscopy.

203.2 See Appendix G.

203.3 N/A

203.4 N/A

203.5 Fluoroscopy

a. Because the primary protective barrier cannot be removed by the user, it will intercept the x-rays whenever they are produced.

b. Fluoroscopic x-ray production is initiated and continued by depressing and maintaining pressure on a momentary or dead-man switch.

c. Cumulative on-time of the fluoroscopic tube must be set prior to selecting kV range on the x-ray control panel. The cumulative on-time can be preset in minutes and seconds. The maximum cumulative on-time is five (5) minutes.

d. Beyond the completion of any preset cumulative on-time, an audible signal (electronic beeper) sounds continuously during x-ray production as the on-time continues to accumulate. A reset control is provided which recycles the on-time to zero without changing the previous preset cumulative on-time.

- e. The mA and kVp are continuously displayed on the left monitor during fluoroscopy. See Appendix G.
- f. The maximum value of the fluoroscopic entrance exposure rate is less than 5.0 R/min in any mode.
- g. There is no provision for high-level operation beyond 75kV at 100uA.
- h. N/A
- i. Whether or not the fluoroscopic unit is used in conjunction with a recording device, x-ray production is terminated when pressure is removed from the momentary (dead-man) control switch.
- j. See Sections 305.0, 306.0, 309.0 and 310.0, Part 300.

204.0 High Voltage Generators

- 204.1 Applications:
General purpose mobile fluoroscopy.
- 204.2 Generator Type:
High Frequency
- 204.3 N/A

205.0 Image Intensifiers

- 205.1 The system identified in this report is a mobile fluoroscope and is image intensified.
- 205.2 See Section 203.5, (a).
- 205.3 See Section 203.0.
- 205.4 N/A
- 205.5 See Section 306.0 and 308.0, Part 300.

206.0 N/A

207.0 N/A

208.0 N/A

PART 300 - QUALITY CONTROL TESTING

301.0 Leakage Radiation from the Diagnostic Source Assembly

Note: For this report Prototype testing was conducted on Premier system Serial # 04-0300-21.

301.4 Prototype Testing

- a. The Tube Housing Assembly Combined with the Beam Limiting Device was tested using the maximum technique of 75 kVp, 100 uA. Ten points were selected and measured, one meter away, under the above conditions.
- b. Eberline RO-5E, serial number 355.
- c. Leakage Radiation raw data in micro R/h:

Top	0	30 Degrees Right	0
45 Degrees Left	0	60 Degrees Right	0
Left	0	Right	0
135 Degrees Left	0	120 Degrees Right	0
Bottom	0	150 Degrees Right	0

- d. Not Applicable

301.5 Production Testing

- a. All production systems will be direct tested.
- b. Not Applicable
- c. Not Applicable
- d. Refer to pages 17 & 18, Appendix I, Test Procedure No. (WINS017)
- e. Same as 301.4 b.
- f. Refer to pages 17 & 18, Appendix I, Test Procedure No. (WINS017)
- g. See Test Form No. (QF070) included in Appendix I
- h. Not Applicable
- i. Production Tested 100%

301.6 Assembler Testing

Not Conducted

302.0 Beam Quality

302.4 Prototype Testing

- a. The Radiation Probe was placed twelve (12) inches from the Beam-Limiting Device. An exposure was made at 75 kVp, 100 uA. Another exposure was made with 2.6 millimeters of aluminum placed at the port of the beam-limiting device using the same technique factors and two results compared.
- b. RadCal Model 1015, serial number 2755, with Model 10X5-6, serial number 13739.
- c. Beam Quality Raw Data - 1st exposure 246 mR/min
2nd exposure 123 mR/min

The Radiation output after the 2nd exposure was approximately equal to 50% of the radiation output after the 1st exposure. Therefore the HVL is 2.5 mm which is greater than the minimum required of 2.3 mm.

- d. Not Applicable

302.5 Production Testing

- a. All production systems will be direct tested.
- b. Not Applicable
- c. Not Applicable
- d. Refer to page 15, Appendix I (Test Procedure)
- e. Keithley Model 35055 Dosimeter with Model 96035 probe.
- f. Refer to page 15, Appendix I (Rejection Limits)
- g. See Test Form No. QF070, included in Appendix I
- h. Not Applicable
- i. Production tested 100%

302.6 Assembler Testing

Not Conducted

303.0 Aluminum Equivalence

Not Applicable

304.0 Standby Radiation from Capacitor Energy Storage Equipment

Not Applicable

305.0 Fluoroscopic Entrance Exposure Rate

305.4 Prototype Testing

- a. The Fluoroscopic Entrance Exposure Rate was measured at a distance of 9cm from the Source Assembly with the tube potential and current set at 75 kVp, 100 μ A.
- b. Radcal Model 10X-5-6 Probe
- c. The Entrance Exposure rate was measured at 3.60 R/min.
- d. Not Applicable

305.5 Production Testing

- a. All systems will be direct tested.
- b. Not Applicable
- c. Not Applicable
- d. Refer to Page 14, Appendix I (Test Procedure)
- e. Radcal Model 10X-5-6 Probe
- f. Refer to Page 14, Appendix I (Rejection Limits)
- g. See Test Form No. (QF070) included in Appendix I
- h. Not Applicable
- i. Production tested 100%

305.6 Assembler Testing

Not Conducted

306.0 Primary Protective Barrier Transmission

306.4 Prototype Testing

- a. The EER was determined as defined in section 305. The Primary Protective Barrier Transmission rate was measured by placing an attenuation block midway between the Beam-Limiting Device and the II. The area below the plane of the II was scanned at a distance of ten centimeters from the II.
- b. Eberline RO-5E, serial number 355.
- c. Entrance Exposure rate was 3.60 R/min. Worst case exposure rate due to transmission through the primary barrier was 3.0 mR/hr. at all points measured above the plane of the II.

d. Not Applicable

306.5 Production Testing

a. All systems will be direct tested.

b. Not Applicable

c. Not Applicable

d. Refer to Page 17, Appendix I (Test Procedure)

e. Radcal Model 1015 Rad. Monitor with Radcal Model 10x5-1800 Probe

f. Refer to Page 17, Appendix I (Rejection Limits)

g. See Test Form No.(QF070) included in Appendix I

h. Not Applicable

i. Production Tested 100%

306.6 Assembler Testing

Not Conducted

307.0 Reproducibility and Linearity

Not Applicable

308.0 Radiation from Components other than the Diagnostic Source Assembly

308.4 Prototype Testing

a. The Image Intensifier Assembly and the X-Ray Control were scanned at a distance of 5 centimeters from any accessible surface using the Radcal 1015 Rad. Monitor and 10x5-1800 Probe. No readings greater than 0 could be found. Eight points were selected and measurements recorded.

b. Eberline RO-5E, serial number 355.

c. Leakage Radiation Raw Data in mR/h:

Top	0	Bottom	0
45 Degrees Left	0	135 Degrees Right	0
90 Degrees Left	0	90 Degrees Right	0
135 Degrees Left	0	45 Degrees Right	0

d. Not Applicable

308.5 Production Testing

- a. Production Testing is not conducted. It is believed that the manufacturing and Quality Assurance procedures relating to assembly are sufficient to insure that the device will meet the requirements of the Standard.

308.6 Assembler Testing

Not Conducted

309.0 Peak tube Potential

309.4 Prototype Testing

- a. Ten (10) exposures were made at each of fourteen (14) different pre-selected mA and kVp settings. The actual mA's were calculated as defined in 309.4d. All mA readings were well within the test limits designated.
- b. Fluke Model 78 Multimeter
- c. See Prototype test report attached as Attachment 1
- d. The tube current has a 49.9K ohm, 1% resistor in the circuit. All high voltage current must go through this resistor. Therefore, 49900 times 0.000001 equals 0.0499 volts or 0.05 volts per uAmp.

The high voltage divider to measure the kV draws 25 uAmps at 75 kV. This must be subtracted to find the tube current.

309.5 Production Testing

- a. All systems will be direct tested.
- b. Not Applicable
- c. Not Applicable
- d. Refer to Page 13, Appendix I (Test Procedure)
- e. Fluke Model 78 Multimeter
- f. Refer to Page 13, Appendix I (Rejection Limits)
- g. See Test Form No. (QF070) included in Appendix I
- h. Not Applicable
- i. Production Tested 100%

310.0 Tube Current

310.4 Prototype Testing

- a. Ten (10) exposures were made at each of fourteen (14) different pre-selected mA and kVp settings. The actual kVp's were calculated as defined in 310.4d. All kVp readings were well within the test limits designated.
- b. Fluke Model 78 Multimeter
- c. See Prototype test results attached as Attachment 1
- d. The system has a resistor divider network using 1% resistors. This divider produces 0.033 volts for each kV of input.

Example: If a reading of 2.31 volts is obtained, the reading is divided by 0.033 which equals 70 kV.

310.5 Production Testing

- a. All systems will be direct tested.
- b. Not Applicable
- c. Not Applicable
- d. Refer to Page 13, Appendix I (Test Procedure)
- e. Fluke Model 78 Multimeter
- f. Refer to Page 13, Appendix I (Rejection Limits)
- g. See Test Form No. (QF070) included in Appendix I
- h. Not Applicable
- i. Production Tested 100%

310.6 Assembler Testing

Not Conducted

311.0 thru 320.0 - Not applicable

321.0 Alignment of X-Ray Field with Fluoroscopic Image Intensifier

321.4 Prototype Testing

- a. A fixture made with a Lanex screen was placed directly on the image intensifier. A fluoroscopic exposure was made and the illuminated area of the Lanex screen was measured. Because the system has fixed collimation and a fixed SID, only one measurement is required. To confirm the accuracy of the alignment of the x-ray field to the image intensifier and the size of the x-ray field at the plane of the image intensifier for the fixture used, a second test was conducted on this prototype system. The test utilized a Nuclear Associates Model 07-600 Fluoroscopic Beam Alignment Device. This device consists of a plate into which channels have been cut to accept four (4) sliding brass strips. The strips define the visible area of the image receptor, and they are adjustable with respect to the center of the device. The holes drilled at 1/2" intervals on a line through the center of each channel are filled with radiopaque plugs. The clear visibility of the plugs in the fluoroscopic image permits their use as a means of centering the device. The size of the field can be determined by counting the number of visible plugs from one edge of the field to the opposite edge, and multiplying that number by one-half to give the value in inches. A transparent plastic overlay on the aluminum plate prevents the vertical displacement of the brass strips.
- b. No test equipment was required for this test, only a fixture made with a Lanex screen.
- c. The diameter of the image intensifier is 15 cm. The illuminated area of the Lanex screen, or the area of the x-ray beam at the plane of the entrance of the image intensifier was measured to be 4.9" and centered on the image intensifier.
- d. Not Applicable

321.5 Production Testing

- a. All systems will be direct tested as per the procedure included in Appendix I
- b. Not Applicable
- c. Not Applicable
- d. See Page 15, Appendix I, (Test Procedure)
- e. N/A - no instruments are required
- f. See page 15, Appendix I (Test Procedure)
- g. See Test Form No. (QF070) included in Appendix I
- h. Not Applicable
- i. Production tested 100%

321.6 Assembler Testing

Not Conducted

322.0 through 325.0 - Not Applicable

Part 400 - Common Aspects

Same as previously reported.